DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: GEMZAR™
Docket No. 96E-0314

#16

JUL - 8 1997

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,808,614 filed by Eli Lily & Company under 35 U.S.C. § 156.

A letter sent to you dated March 7, 1997 incorrectly stated in the opening paragraph:

> The human drug product claimed by the patent is GEMZAR™ (gemcitabine hydrochloride), which was assigned New Drug Application (NDA) No. 20-509.

In fact, the statement should have read:

> The human drug product identified in the patent extension application is GEMZAR™ (gemcitabine hydrochloride), which was assigned New Drug Application (NDA) No. 20-509.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Margaret Brumm
Eli Lilly & Company
Patent Division/MMB
Lilly Corporate Center
Indianapolis, IN 46285